DEPARTMENT OF HEALTH & HUMAN SERVICES
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, Maryland 21244-1850

Tracking Form for Applicants for New Technology Add-on Payments under the Acute Inpatient Prospective Payment System (IPPS)

1. Technology Name:

   Kinetra® dual-channel, implantable, neurostimulator for deep brain stimulation

2. Manufacturer Name:

   Medtronic, Inc.

3. Trade Brand of Technology:

   Kinetra® dual-channel, implantable, neurostimulator for deep brain stimulation

4. Brief Description of Service or Device:

   The Kinetra® implantable neurostimulator is designed to deliver electrical stimulation to the subthalamic nucleus (STN) or internal globus pallidus (GPi). Before the development of Kinetra, treating bilateral symptoms of patients with Essential Tremor and Parkinson's disease required the implantation of two neurostimulators – one for the right side of the brain (to control symptoms on the left side of the body), the other for the left side of the brain (to control symptoms on the right side of the body). The development of a single neurostimulator that treats bilateral symptoms provides a less invasive treatment option for patients and simpler implantation, follow-up care, and programming procedures for physicians. The Kinetra neurostimulator, implanted in the pectoral area, is designed to eliminate the need for two devices by accommodating two leads that are placed in both the left and right sides of the brain to deliver the necessary impulses. Neurostimulation is intended to block errant brain signals that cause symptoms.

New Criteria

Note: To qualify for a new technology add-on payment, the technology or service must not be reflected in the data used to establish the diagnosis related groups (DRGs).

(For the complete application requirements, please see the instructions at http://cms.hhs.gov/providers/hipps/10_03_application.zip**)**
Note: The information provided on this tracking form will be made publicly available.

5. Date of Food and Drug Administration (FDA) approval (or expected approval) for the device or service:

   Kinetra® is currently being reviewed by the FDA. Approval is anticipated in the first quarter of 2004.

6. Does the technology have an International Classification of Diseases, Ninth Revision, Clinical Modification (ICD-9-CM) procedure code(s) or is an application pending?

   a. If yes, please provide the ICD-9-CM procedure code(s) used to identify the clinical procedure(s) with which the medical service and technology is used.

   b. If there is no existing ICD-9-CM code that captures this new technology, please indicate whether you will be applying for a new code. (Refer to http://www.cms.hhs.gov/paymentsystems/icd9 for more information.)

No existing ICD-9-CM procedure code captures this new technology. Medtronic submitted a request to the ICD-9-CM Coordination and Maintenance Committee for the December 4, 2003 meeting to revise the current neurostimulator codes, including the creation of a unique code for the insertion of dual array neurostimulators.

7. Have you submitted an application for outpatient pass-through payments under the Medicare outpatient prospective payment system? If so, please provide the tracking number or, if it was approved, please provide the date of approval. (Please refer to http://cms.hhs.gov/providers/hopps/apc.asp for more information.)

Yes. Medtronic submitted an outpatient application for pass-through payment under OPPS. The tracking number is 79-CAT

Cost Criteria

Note: To qualify for a new technology add-on payment, the technology or service must result in average charges for cases using the technology in excess of 75 percent of one standard deviation above the average charges for the DRG(s) to which the technology or service is assigned.

Provide the following information to demonstrate the technology or service meets the criterion.

8. What is the anticipated average standardized charge per case involving this new technology? For details how to

standardize charges please refer to the technical appendix of the application form.

Proprietary information provided in the full application to CMS.

9. What is the total estimated cost per case for the service or technology (this will include all costs involved in the case, including the cost of the service or device)? What is the cost of the technology per patient? Please provide a breakdown how the cost of the technology is calculated (i.e. **Drugs**- Average dosage or number of units per patient (ml/kg/hr); **Devices**- breakdown of the cost of all components used in the new technology).

Proprietary information provided in the full application to CMS.

10. List the diagnosis-related groups (DRGs) to which cases involving this new technology will most likely be assigned.

DRGs for Kinetra Deep Brain Stimulation	
DRG	Description
001	Craniotomy, Age Greater than 17 with CC
002	Craniotomy, Age Greater than 17 without CC

11. What is the anticipated volume of Medicare cases involving of this technology (by DRG)?

Because this is the first year with new descriptors and there is not claims data available, projections are being made by applying 2003 criteria to 2002 MedPAR claims data. Application of these results to volume projections are as follows:

Anticipated Kinetra Volume by DRG		
DRG	2004	2005
001	180	360
002	540	1,080
Total	720	1,440

Clinical Improvement

Note: To qualify for a new technology add-on payment, the technology or service must represent a substantial clinical improvement over existing technologies or services

12. Please provide a short synopsis of the following clinical issues added to the new technology. Use the regular application to submit full details.

(For the complete application requirements, please see the instructions at http://cms.hhs.gov/providers/hipps/10_03_application.zip**)**
Note: The information provided on this tracking form will be made publicly available.

a. Briefly describe how the new service or technology represents a substantial clinical improvement over existing services or technologies:

Kinetra provides a range of substantial improvements beyond previously available technology.

Reduced rate of device-related complications and hospitalizations or physician visits
Less trauma and tunneling:
The deep brain stimulation (DBS) population is often an elderly and frail one. As a general rule, physicians are leery to expose them to more surgery than what is necessary. For those patients requiring bilateral lead implants, one Kinetra serves the same function as two single-channel Soletra neurostimulators. Joint and colleagues (2002) of the Radcliffe Infirmary at Oxford have made it standard protocol to implant Kinetra, in lieu of a Soletra, even in those patients who do not need bilateral stimulation. The natural history of certain forms of PD will merit bilateral stimulation sometime in the future and thus, it is better to prevent patients from suffering through multiple arduous surgeries. Moreover, each additional incision compounds the risk of infection, which can result in the explantation of the device. It can be also be argued that multiple incisions retard recovery and worsen post-operative pain. In addition to patient suffering, repeated surgeries escalate the costs of DBS (Hariz, 2002).

Reed switch disablement
A magnetic switch, called a reed switch, allows neurostimulators to be turned on or off by a physician programmer in order to conserve battery power. Unfortunately, the reed switch can be also tripped by electromagnetic inference (EMI). The most common sources of EMI include household devices such as electric shavers, microwaves, electric toothbrushes, electric drills, and other power tools (Volkmann et al., 2002). Other sources of EMI include anti-theft devices at department stores, metal detectors, and magnets in loudspeakers.

There are numerous accounts in the literature of neurostimulators accidentally turning on or off by EMI to the detriment of the patient. Hariz and Johansson (2001) report two patients, both of whom had one of their two Soletra devices accidentally turned off by EMI, and subsequently required emergency hospital admission. Both patients achieved a state of " parkinsonian crisis" with the sudden and unexpected reappearance of severe rigidity and gait freezing. Hariz (2001) stresses the notion that abruptly switching off a neurostimulator can result in a swift and severe return of rigidity, akinesia, and parkinsonian tremor requiring emergency hospital admission. Joint and colleagues (2002) concur with Hariz (2001), who report problems with unpredictable switching on/off of the Itrel II (Soletra) but no such problems

with Kinetra. The Medtronic Technical Services team reports 159 cases of device-related complications of varying severity due to EMI alone.

Kinetra has a reed switch disabling function that physicians can use to prevent inadvertent shut-off of the device. Additionally, Hariz (2002) asserts that the magnetically shielded Kinetra can avoid many of the complications from EMI.

Patient control:
There are a number of complications that could occur when patients cannot adjust their stimulation therapy or monitor battery life. According to Medtronic Technical Services, customers called to report 97 cases of sudden rebound of parkinsonian symptoms due to battery depletion. What's more, when batteries stop without warning patients, they are in the same situation as that reported by Hariz and Johansson (2001) above with accidental on/off switching from EMI. We can expect ER visits from DBS patients when disabling parkinsonian symptoms suddenly reappear. If ER physicians are not savvy about DBS, they may exacerbate, rather than aid, the patient in crisis.

When equipped with the patient programmer, Kinetra patients can monitor battery life. The low battery indicator alerts patients to schedule appointments with their physicians before the onset of disabling symptoms. Vesper and colleagues (2002) agree, " the use of the patient therapy controller increases the comfort and independence of the patient."

Also, this patient controller allows consumers the ability to fine-tune the stimulation therapy within clinician-programmed parameters. Patients can titrate to a level with which they are most comfortable without having to make repeated visits to the physician's office. Last, the patient programmer gives the patient a quick and easy way to verify on/off status. As stated previously, much confusion for the patient stems from not being able to understand the reason for returned parkinsonian symptoms. If the device malfunctioned for any reason, eg, due to EMI or battery end-of-life, the patient therapy controller would let the patient know that immediate medical attention is warranted prior to the onset of a crisis.

Device offers treatment option for a patient population unresponsive to, or ineligible for, currently available treatment
A population that can benefit from Kinetra are those who require higher stimulation rates. Kinetra allows the ability to stimulate above 185 Hz— the limit for Soletra— to 250Hz. The new device has a greater range of voltage settings to allow for better fine-tuning of the neurostimulation therapy. Vesper and authors (2002) mention that one patient in their study population did require these higher stimulation rates.

(For the complete application requirements, please see the instructions at http://cms.hhs.gov/providers/hipps/10_03_application.zip**)**
Note: The information provided on this tracking form will be made publicly available.

b. List of published peer-review articles relevant to the new service or technology.

Hariz MI. Complications of deep brain stimulation surgery. *Movement Disorders*. 2002;17 Suppl:162-166.

Hariz MI and Johansson F. Hardware failure in parkinsonian patients with chronic subthalamic nucleus stimulation is a medical emergency. *Movement Disorders*. 2001;16:166-168.

Joint C, Nandi D, Parkin S, Gregory R, Aziz T. Hardware-related problems of deep brain stimulation. *Movement Disorders*. 2002;17 Suppl:175-180.

VesperJ, Chabardes S, Fraix V, Sunde N, Ostergaard K. Dual-channel deep brain stimulation system (Kinetra) for Parkinson's disease and essential tremor: a prospective multicentre open label clinical study. *J Neurology Neurosurgery & Psychiatry*. 2002;73:275-280.

Volkmann J, Herzog J, Kopper F, Deuschl G. Introduction to the programming of deep brain stimulation. *Movement Disorders*. 2002; 17 Suppl: 181-187.

(For the complete application requirements, please see the instructions at http://cms.hhs.gov/providers/hipps/10_03_application.zip**)**

Note: The information provided on this tracking form will be made publicly available.